Claims 1 and 6-10 have been amended to recite administering intraductally to a patient an agent that increases retrievable secreted ductal fluid in a breast duct. Support for the amendment can be found in the specification at page 5, line 25 which discloses "administering the agent to the patient can be accomplished by a mode comprising administering an agent intraductally..." *See also* specification at page 5, lines 27-28 which discloses "administering an agent intraductally comprises ductal access with a ductal access tool and passing into the duct a sufficient amount of an agent." Claims 1 and 6-10 have also been amended to recite an agent that increases retrievable secreted ductal fluid. Support for the amendment can be found in the specification at page 14 which discloses introduction of a solution and observing the effects on the *secretion* of fluid from breast ducts. Hence, the specification discloses agents that increase secreted ductal fluid.

Rejection of claim 1-11 under 35 U.S.C. 112, second paragraph

Claims 1-11 were rejected under 35 U.S.C. 112, second paragraph. This rejection is respectfully traversed.

Claim 1 was rejected because the phrase "administering an agent to the patient that increases retrievable fluid from a breast duct" was awkward and confusing. Claim 1 has been amended according to the Examiner's suggestion to recite "administering ... to the patient an agent..." Therefore, Applicants believe the rejection is now moot.

Claims 2-5 have been canceled.

Claim 7 has been amended to correct a typographical error.

Claim 8 was rejected because of insufficient antecedent basis for "the increased breast fluid." Claim 8 has been amended to recite "increased retrievable secreted ductal fluid from the breast duct" which has antecedent basis in claim 1. Claim 1 recites "an agent that increases retrievable secreted ductal fluid from a breast duct".

Claim 10 was rejected because of a lack of clear antecedent basis for "retrievable fluid." Claim 10 has been amended to recite "the retrievable secreted ductal fluid" which has antecedent basis in claim 1. Claim 1 recites "an agent that increases retrievable secreted ductal fluid from a breast duct."

Claim 11 was rejected because of a lack of clear antecedent basis for "the step of analyzing." Claim 11 depends from claim 10 which has been amended to recite "the step of analyzing one or more of cells, fluid or other material in the breast duct..." Thus, claim 11 has clear antecedent basis in claim 10.

It is respectfully requested that the rejection be withdrawn, as all grounds of objection have been addressed.

Rejection of claims 1, 2, and 4 under 35 U.S.C. 102(b) over Gunn or Nguyen

Claims 1, 2, and 4 were rejected under 35 U.S.C. 102(b) as being anticipated by Gunn or Nguyen. This rejection is respectfully traversed.

Claims 2 and 4 have been canceled. Claim 1 recites "administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct."

Gunn discloses administration of recombinant human growth hormone to increase breast milk volumes. Gunn's administration of recombinant hGH was by subcutaneous injection (see page 279, col. 2, "Subjects") and not intraductally as recited in claim 1.

Nguyen discloses administering a polysaccharide product orally or by injection. Nguyen does not teach or suggest administering an agent intraductally to the patient. Because neither Gunn nor Nguyen teach each and every aspect of the claim 1 invention, it is respectfully submitted that the rejection is improper and should be withdrawn.

New claims 16-33 are allowable over Gunn and Nguyen. Claim 16 recites accessing the breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device. Neither Gunn nor Nguyen disclose accessing a breast duct with a device. Gunn and Nguyen also do not teach withdrawing a portion of an increased retrievable secreted ductal fluid into the device. Therefore, claim 16 is allowable over Gunn and Nguyen.

Claims 17-21 and 28-33 depend from claim 16 and are allowable for at least the reasons set forth above for claim 16. Claims 22-27 depend from claim 1 and are allowable for at least the reasons set forth above for claim 1.

Rejection of claims 1 and 2 under 35 U.S.C. 102(b) over Hutchens

Claims 1 and 2 were rejected under 35 U.S.C. 102(b) as being anticipated by Hutchens. This rejection is respectfully traversed.

Claim 1 as amended recites "administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct." Claim 2 has been canceled.

Hutchens discloses topical administration of castor oil to increase breast milk production but does not teach or suggest administering an agent intraductally to the patient. Because Hutchens does not teach each and every aspect of claim 1, it is respectfully submitted that the rejection is improper and should be withdrawn.

New claims 16-33 are also allowable over Hutchens. Claim 16 recites accessing the breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device. Hutchens does not teach accessing a breast duct with a device. Hutchens also does not teach withdrawing a portion of an increased retrievable secreted ductal fluid into the device. Therefore, claim 16 is allowable over Hutchens.

Claims 17-21 and 28-33 depend from claim 16 and are allowable for at least the reasons set forth above for claim 16. Claims 22-27 depend from claim 1 and are allowable for at least the reasons set forth above for claim 1.

Rejection of claims 1, 2, 4, 8, and 10 under 35 U.S.C. 102(b) over Horrobin

Claims 1, 2, 4, 8, and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin. This rejection is respectfully traversed.

Claims 1, 8, and 10 as amended recite "administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct." Claims 2 and 4 have been canceled.

Horrobin discloses oral or parenteral administration of compounds to increase the flow of milk during lactation but does not teach or suggest administering compounds intraductally to the patient. Because Horrobin does not teach each and every aspect of claim 1, it is respectfully submitted that the rejection is improper and should be withdrawn.

Claims 8 and 10 depend from claim 1 and are allowable for at least the reasons set forth for claim 1 above.

New claims 16-33 are also allowable over Horrobin. Claim 16 recites accessing the breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device. Hutchens does not teach accessing a breast duct with a device. Hutchens also does not teach withdrawing a portion of an increased retrievable secreted ductal fluid into the device. Therefore, claim 16 is allowable over Hutchens.

Claims 17-21 and 28-33 depend from claim 16 and are allowable for at least the reasons set forth above for claim 16. Claim 22-27 depend from claim 1 and are allowable for at least the reasons set for above for claim 1.

Rejection of claims 1-3, 5, and 8-11 under 35 U.S.C. 102(e) over Love or Barsky

Claims 1-3, 5, and 8-11 were rejected under 35 U.S.C. 102(e) as being anticipated by Love or Barsky. This rejection is respectfully traversed.

Claims 1 and 8-11 as amended recite "administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct." Claims 2-5 have been canceled.

Love and Barsky are cited as disclosing administration of saline into a duct of a breast. Barsky is further cited as disclosing topical administration of an ointment containing acetic acid and Velvacrol to release keratin plugs in a nipple. However, Love and Barsky do not administer any of the agents as recited in claim 1. Because Love and Barsky do not teach each and every aspect of claim 1, it is respectfully submitted that the rejection is improper and should be withdrawn. Claims 8-11 and new claims 22-27 depend from claim 1 and are allowable for at least the reasons set forth above for claim 1.

New claim 16 is also allowable over Love and Barsky because Love and Barsky do not teach any of the agents recited in claim 16. Because Love and Barsky do not teach each and every aspect of claim 16, the rejection is improper and should be withdrawn.

New claims 17-21 and 28-33 depend from claim 16 and are allowable for at least the reasons set forth for claim 16.

Rejection of claims 1, 2, 4, and 8-11 under 35 U.S.C. 102(e) over Quay

Claims 1, 2, 4, and 8-11 were rejected under 35 U.S.C. 102(e) as being anticipated by Quay. This rejection is respectfully traversed.

Claims 1 and 8-11 as amended recite "administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct." Quay discloses administration of oxytocin intranasally, intramuscularly or intravenously but does not teach or suggest administering compounds intraductally to the patient. Quay thus does not teach each and every aspect of claim 1. The rejection should therefore be withdrawn.

Claims 2 and 4 have been canceled. Claims 8-11 and claims 22-27 depend from claim 1 and are allowable for at least the reasons set forth above for claim 1.

Claim 16 recites accessing the breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device. Quay does not teach accessing the breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device. Rather, Quay merely discloses applying a breast pump to the surface of the breast to exert negative pressure to facilitate expression from breast ducts. Expressed fluid from the breast ducts is collected from the surface of the breast. See, *e.g.*, col. 11, lines 28-33. Thus, Quay does not teach accessing the breast duct with the device because the breast pump of Quay does not access the breast duct. Therefore, claim 16 is allowable over Quay. Claim 17-21 depend from claim 16 and are allowable for at least the reasons set forth for claim 16.

Rejection of claims 1, 2, 5, 6, and 8-11 under 35 U.S.C. 103(a) over Ogata

Claims 1, 2, 5, 6, and 8-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ogata. This rejection is respectfully traversed.

Claims 1, 6, and 8-11 as amended recite administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct. Ogata discloses injecting ozone into a teat orifice of a cow in order to treat mastitis by killing infected disease-causing microbes. An ozone injection nozzle is used to inject an ozone jet into a breast of a cow "to increase surface areas sensitized to disease-causing microbes residing within infected milk." See, *e.g.*, col. 6, lines 58-56. Nowhere does Ogata teach or suggest injecting any of the recited agents of claim 1 into the teat of the cow. Moreover, it would not have been obvious to one of ordinary skill in the art at the time the invention was made to administer one of the recited agents that increases retrievable secreted ductal fluid from a breast duct in view of the disclosure of Ogata which does not teach or suggest administering any agents that increase retrievable secreted ductal fluid in a breast duct but rather teaches treating mastitis. It is respectfully submitted that the rejection should be withdrawn.

Claim 2 and 5 have been canceled. Claims 6, 8-11and 22-27 depend from claim 1 and are allowable for at least the reasons set forth for claim 1 above.

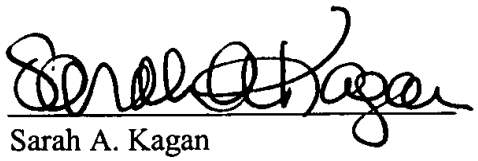
New claims 16-21 are also allowable over Ogata. Claim 16 recites accessing the breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device. Ogata does not teach or suggest accessing the breast duct

with a device and withdrawing a portion of the increased retrievable ductal fluid into the device as required by claim 16. Ogata merely injects ozone into the cow but does not access the breast duct with a device and withdraw a portion of increased retrievable ductal fluid into the device. Ogata does not teach or suggest increased retrievable ductal fluid at all. Thus, claim 16 is allowable over Ogata.

Claims 17-21 and 28-33 depend from claim 16 and are allowable for at least the reasons set forth for claim 16.

Applicants respectfully submit that the instant application is in condition for allowance. If the Examiner feels, however, that further amendment and/or discussion may be helpful in facilitating prosecution of the case, the Examiner is respectfully requested to telephone the undersigned attorney of record at the number appearing below.

Respectfully submitted,



Sarah A. Kagan
Registration No. 32,141

BANNER & WITCOFF, LTD.
1001 G Street, N.W.
Washington, D.C. 20001
(202) 508-9100

Date: September 9, 2002

MARKED-UP VERSION OF AMENDMENT

Please amend claims 1 and 6-10 as follows:

1. (Amended) A method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising:

administering [an agent] intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct, wherein the agent is selected from the group consisting of a hypotonic solution, a buffered solution, a solution having a pH range of human tissue, blood or sera, a solution having a slightly acid pH, a solution having a slightly basic pH, a nonabsorbable biocompatible solution, a protein, a colloid, a sugar, a polymer, mannitol, sorbitol, glucose, glycerol, sucrose, raffinose, fructose, lactulose, polyethyleneglycol (PEG), maltodextrin, dextran, dextran 70, hydroxyethyl starch, fluid gelatin, a synthetic colloid, an antibody, a binding protein, albumin, a hormone, a natural herb, an extract from a natural herb, silymarin, a surfactant, a growth factor, oxytocin, prolactin, an organic molecule, a muscle relaxant, and a ductal orifice dilator.

6. (Amended) A method as in claim [2] 1, wherein the agent is [intraductally administered and the agent is] in a state selected from the group consisting of a non-liquid, a gel, an emulsion, a gas and a semi-solid.

7. (Amended) A method as in claim [2] 1, wherein the agent [is intraductally administered agent and the agent] comprises a carbonated fluid comprising super oxygenated fluid that is colder than room temperature before [intraductal] administration.

8. (Amended) A method as in claim 1, further comprising collecting a portion of the increased [breast duct] retrievable secreted ductal fluid from [a] the breast duct.

9. (Amended) A method as in claim 8, wherein collecting comprises accessing a breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device.

10. (Amended) A method as in claim 8, further comprising the step of analyzing one or more of cells, fluid or other material in the breast duct after the retrievable secreted ductal fluid has been increased and a portion of it has been collected.